

July 30, 2010

BY ELECTRONIC DELIVERY

Louis Jacques, MD
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop S3-02-01
7500 Security Blvd.
Baltimore, MD 21244

**Re: NCA Tracking Sheet for Autologous Cellular Immunotherapy
Treatment of Metastatic Prostate Cancer (CAG-00422N)**

Dear Dr. Jacques:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the opening of a national coverage analysis (NCA) for autologous cellular immunotherapy treatment of metastatic prostate cancer.¹ BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the world. BIO represents more than 1,200 biotechnology centers, academic institutions, state biotechnology centers, and related organizations in the United States and in more than 30 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

In particular, many of our members are involved in the research and development of cancer therapies and play a critical role in delivering treatments that both prolong life and reduce the burden of disease for cancer patients worldwide. As such, BIO has a particular interest in CMS actions that may limit patient access to novel therapies.

BIO is concerned about CMS's decision to open an NCA on a recently-approved therapy because it could establish a precedent that affects Medicare patient access to a wide range of innovative drug and biological therapies on a national basis. We

¹ NCA Tracking Sheet for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N), June 30, 2010.



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are concerned that the NCA could curtail labeled and appropriate uses of a Food and Drug Administration (FDA) approved therapy, particularly before the medical community has the opportunity to develop experience with the labeled use of the therapy. As we have commented previously, as a general policy, BIO strongly urges CMS to follow sound principles of evidence-based medicine in formulating coverage policies.

This NCA is focused on a new therapy, Provenge, recently approved by the FDA under section 351(a) of the Public Health Service Act as an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.² The statutory definition of “drugs and biologicals” that may be covered by Medicare includes “any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication.”³ The statute explicitly recognizes any use that has been approved by the FDA as a “medically accepted indication” of a drug or biological used in an anticancer chemotherapeutic drug regimen.⁴ By questioning whether this therapy should be covered for its labeled indication, CMS risks contravening the statute and challenging Congressional intent to protect access to approved drugs and biologicals used to treat cancer. There should be no question that an approved therapy should be covered for the patients and conditions indicated on its label. If there is a safety issue associated with the labeled indication, the FDA would be the logical responsible Federal agency to consider modification of the label. The FDA had that opportunity to modify the label before approval of this therapy and did not do so.

BIO urges CMS to consider the impact of its actions on the stakeholder and patient community. When CMS initiates an NCA on a technology, its action often is perceived by Medicare contractors, other payers, and the investment community as a sign that they should withhold coverage or support until the NCA is concluded. Although CMS may not intend for the opening of an NCA to have these effects, it is critical that CMS take care to ensure that its decisions do not harm access to care for existing technologies and continued development of new therapies. Given these concerns about patient access and in light of the recent FDA approval and statutory protections for approved drugs and biologicals used to treat cancer, we ask that CMS conclude the NCA as quickly as possible.

² FDA Approval Letter for Provenge, April 29, 2010.

³ Social Security Act (SSA) § 1861(t)(2)(A).

⁴ SSA § 1861(t)(2)(B).

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Finally, BIO appreciates that CMS has created an opportunity for public feedback with the announcement of this NCA. Maintaining transparency and open lines of communication with stakeholders about technologies under consideration for review will be essential as CMS moves toward implementing the recent Memorandum of Understanding with the FDA and seeks manufacturers' cooperation in sharing trade secret and sensitive data with CMS prior to FDA approval to facilitate the coverage process. Should CMS decide to proceed with the Medicare Evidence Development and Coverage Advisory Committee meeting, BIO urges CMS to make publicly available the questions asked of the panel in advance of the meeting as it typically does. Additionally, should CMS proceed with the technology assessment, we request that CMS make publicly available the research questions to be addressed.

BIO appreciates the opportunity to submit these comments. We urge CMS to conclude this NCA as quickly as possible without limiting coverage of Provenge for its approved indication. Instead, CMS should treat this therapy just as it treats other new drugs and biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication. Please contact me at (202) 962-9220 if you have any questions regarding these comments. Thank you for your attention to these very important matters.

Respectfully submitted,

/s/

Laurel Todd
Director, Reimbursement and
Health Policy